## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicant:** 

Robert M Townsend, et al. Examiner:

Phillip Gambel, Ph.D.

Serial No.:

1.<del>09/887,987</del>

**Group Art Unit:** 

1644

Filed:

June 8, 2001

**Docket No.:** 

30436.53USU1

Title:

METHODS FOR REGULATING A CELL-MEDIATED IMMUNE

RESPONSE BY BLOCKING LYMPHOCYTIC SIGNALS AND BY

**BLOCKING LFA-1-MEDIATED ADHESION** 

CERTIFICATE UNDER 37 C.F.R. §1.8:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 27, 2004.

Renato Marco Domingo

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(c)(2))

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

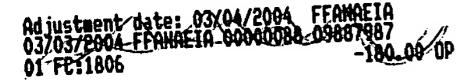
This Information Disclosure Statement is being filed herein as a supplement to Applicant's October 26, 2001, December 10, 2002, January 14, 2003, and June 16, 2003, Information Disclosure Statements which were submitted under 37 C.F.R. §§1.97(b)(3) or 1.97(c)(2). In accordance with 37 C.F.R. §1.98(d), copies of Exhibits 233-248 as set forth in the Form 1449 are included herein. Additionally, in accordance with 37 C.F.R. §1.97(c)(2), a check in the amount of \$180.00 to cover the fee under 37 C.F.R. §1.17(p) is enclosed.

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner. These are as follows:

03/03/2004 FFANAEIA-00000088 09887987/

01 FC:1806

180.00 OP



03/04/2004 FFAMMEIA 00000067 09877987

Robert M. Townsend, et al. Serial No. 09/887,987

Filed: June 8, 2001

Page 2

- International Published Application No. WO96/23071 published August 1, 1996 Exhibit
   233
- International Published Application No. WO94/01547 published January 20, 1994 Exhibit
   234
- International Published Application No. WO95/06481 published March 9, 1995 Exhibit
   235
- International Published Application No. WO95/28957 published November 2, 1995 –
   Exhibit 236
- Bluestone, Jeffrey A., "New Perspectives of CD28-B7-Mediated T Cell Costimulation,"
   Immunity, 1995, 2:555-9 Exhibit 237
- Bluestone, J. A., "Costimulation and its role in organ transplantation," Clin. Transplantation, 1996, 10:104-9 Exhibit 238
- Chen, Fang-An et al., "Human Antibody Response in Human Peripheral Blood Leukocyte/Severe Combined Immunodeficient Chimeric Model is Dependent on B and T Cell Costimulation via CD40/CD40 Ligand," *Journal of Immunology*, 1995, 155:2833-40 –
   Exhibit 239
- Durie, Fiona H. et al., "Prevention of Collagen-Induced Arthritis with an Antibody to gp39, the Ligand for CD40," Science, 1993, 261:1328-30 Exhibit 240
- Durie, Fiona H. et al., "Antibody to the Ligand of CD40, gp39, Blocks the Occurrence of the Acute and Chronic Forms of Graft-vs-Host Disease," Journal of Clinical Investigation, 1994, 94:1333-8 Exhibit 241
- Griggs, Nathan et al., "Contribution of CD28/CTLA4/B7 and gp39/CD40 Costimulation Pathways in Clonal Expansion and Functional Acquisition of Self Reactive T Cells," *Journal* of Cellular Biochemistry, 1995, Supplement, p. 141, C2-427 – Exhibit 242
- Jenkins, Marc K. et al., "CD28 Delivers a Costimulatory Signal Involved in Antigen-Specific IL-2 Production by Human T Cells," Journal of Immunology, 1991, 147:2461-6 Exhibit 243

Robert M. Townsend, et al.

Serial No. 09/887,987

Filed: June 8, 2001

Page 3

• Lenschow, Deborah J. et al., "Inhibition of Transplant Rejection Following Treatment with

Anti-B7-2 and Anti-B7-1 Antibodies," Transplantation, 1995, 60:1171-8 - Exhibit 244

• Rossini, Aldo A. et al., "Induction of Immunological Tolerance to Islet Allografts," Cell

*Transplantation*, 1996, 5:49-52 – **Exhibit 245** 

• Roy, Meenakshi et al., "Studies on the interdependence of gp39 and B7 expression and

function during antigen-specific immune response," European Journal of Immunology, 1995,

25:596-603 – Exhibit 246

• Schaub, M. et al., "Synergistic effect of CD40L/CD40 and CD28/B7 Blockade in murine

EAE," Journal of Allergy and Clinical Immunology, 1997, 99:5206, Abstract 843 - Exhibit

247

• Tang, Aimin et al., "Suppression of Murine Allergic Contact Dermatitis by CTLA4Ig:

Tolerance Induction of Th2 Responses Requires Additional Blockade of CD40-Ligand,"

Journal of Immunology, 1996, 157:117-25 - Exhibit 248

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102

and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish

that the reference(s) are not "prior art." Moreover, Applicants do not represent that the

references have been thoroughly reviewed or that any relevance of any portion of a reference is

intended.

Consideration of the items listed is respectfully requested. Applicants invite the Patent Office to

request additional information if necessary. Pursuant to the provisions of M.P.E.P. 609, it is

requested that the Examiner return a copy of the attached Form 1449, marked as being

considered and initialed by the Examiner, to the undersigned with the next official

communication.

Robert M. Townsend, et al. Serial No. 09/887,987

Filed: June 8, 2001

Page 4



No fee, other than the \$180.00, is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-0306.

Respectfully submitted,

Sarah B. Adriano

Registration No. 34,470

Teresa Liang

Registration No. 51,946

Mandel & Adriano

55 South Lake Avenue, Suite 710

Pasadena, California 91101

(626) 395-7801

Customer No. 26,941



### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicants:** 

Robert M. Townsend et al.

Serial No.:

09/877,987

Filed:

June 8, 2001

Docket:

D0009NP/30436.53USU1

Title:

METHODS FOR REGULATING A CELL-MEDIATED IMMUNE RESPONSE BY

BLOCKING LYMPHOCYTIC SIGNALS AND BY BLOCKING LFA-1-MEDIATED

**ADHESION** 

#### **CERTIFICATE UNDER 37 CFR 1.8:**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 27, 2004.

55 S. Lake Avenue, Suite 710 Pasadena, California 91101 February 27, 2004

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

We are transmitting herewith the attached:

Transmittal sheet, in duplicate, containing Certificate under 37 CFR §1.8

Supplemental Information Disclosure Statement (37 C.F.R. §1.97 (c)(2))

Form 1449 (Information Disclosure Statement)

**Exhibits 233-248** 

Return postcard

Please charge any additional fees or credit overpayment to Deposit Account No. 50-0306. A duplicate of this sheet is enclosed.

MANDEL & ADRIANO

55 South Lake Avenue, Suite 710 Pasadena, California 91101

(626) 395-7801

Name: Sarah B. Adriano

By: Stuck B. Adia

Reg. No.: 34,470 Initials: SBA

FORM 1449*	Docket Number	Application Number
OIPE	30436.53USU1	09/887,987
MFORMATION DISCLOSURE STATEMENT	Applicants	
IN AN APPLICATION	Robert M. Townsend e	et al.
MAR 0 2 2004 H	Filing Date	Group Art Unit
(Use several sheets if necessary)	June 8, 2001	1644

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

		FOREIGN PATE	NT DOCUMENT	S			
	DOCUMENT NO. DATE COUNTRY CLASS SUBCLASS				TRANSLATION		
•						YES	NO
	WO 96/23071 (Exhibit 233)	08/01/96	PCT				X
•	W094/01547 (Exhibit 234)	01/20/94	PCT				Х
	W095/06481 (Exhibit 235)	03/09/95	PCT				Х
	W095/28957 (Exhibit 236)	11/02/95	PCT				Х

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	Bluestone, Jeffrey A., "New Perspectives of CD28-B7-Mediated T Cell Costimulation," <i>Immunity</i> , 1995, 2:555-9 (Exhibit 237)
	Bluestone, J. A., "Costimulation and its role in organ transplantation," Clin. Transplantation, 1996, 10:104-9 (Exhibit 238)
7	Chen, Fang-An et al., "Human Antibody Response in Human Peripheral Blood Leukocyte/Severe Combined Immunodeficient Chimeric Model is Dependent on B and T Cell Costimulation via CD40/CD40 Ligand," <i>Journal of Immunology</i> , 1995, 155:2833-40 (Exhibit 239)
•	Durie, Fiona H. et al., "Prevention of Collagen-Induced Arthritis with an Antibody to gp39, the Ligand for CD40," Science, 1993, 261:1328-30 (Exhibit 240)
	Durie, Fiona H. et al., "Antibody to the Ligand of CD40, gp39, Blocks the Occurrence of the Acute and Chronic Forms of Graft-vs-Host Disease," <i>Journal of Clinical Investigation</i> , 1994, 94:1333-8 (Exhibit 241)
	Griggs, Nathan et al., "Contribution of CD28/CTLA4/B7 and gp39/CD40 Costimulation Pathways in Clonal Expansion and Functional Acquisition of Self Reactive T Cells," <i>Journal of Cellular Biochemistry</i> , 1995, Supplement, p. 141, C2-427 (Exhibit 242)
1	Jenkins, Marc K. et al., "CD28 Delivers a Costimulatory Signal Involved in Antigen-Specific IL-2 Production by Human T Cells," <i>Journal of Immunology</i> , 1991, 147:2461-6 (Exhibit 243)
	Lenschow, Deborah J. et al., "Inhibition of Transplant Rejection Following Treatment with Anti-B7-2 and Anti-B7-1 Antibodies," <i>Transplantation</i> , 1995, 60:1171-8 (Exhibit 244)
	Rossini, Aldo A. et al., "Induction of Immunological Tolerance to Islet Allografts," Cell Transplantation, 1996, 5:49-52 (Exhibit 245)

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation	
if not in conformance and not considered. Include copy of this t	form for next communication to the Applicant.
*Substitute Disclosure Statement Form (PTO-1449) P	atent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Number

	FORM 1449*
	OIPE
	NFC
BET	MAR 0 2 2004 W
B	C RADEMPRE

# FORMATION DISCLOSURE STATEMENT IN AN APPLICATION

30436.53USU1 09/887,987

Applicants
Robert M. Townsend et al.

Filing Date Group Art Unit

1644

**Docket Number** 

June 8, 2001

(Use several sheets if necessary)

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	Roy, Meenakshi et al., "Studies on the interdependence of gp39 and B7 expression and function during antigen-specific immune response," <i>European Journal of Immunology</i> , 1995, 25:596-603 (Exhibit 246)
	Schaub, M. et al., "Synergistic effect of CD40L/CD40 and CD28/B7 Blockade in murine EAE,"  Journal of Allergy and Clinical Immunology, 1997, 99:5206, Abstract 843 (Exhibit 247)
	Tang, Aimin et al., "Suppression of Murine Allergic Contact Dermatitis by CTLA4lg: Tolerance Induction of Th2 Responses Requires Additional Blockade of CD40-Ligand," Journal of Immunology, 1996, 157:117-25 (Exhibit 248)
•	
•	
ŧ	
•	
,	

EXAMINER	DATE CONSIDERED	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

<sup>\*</sup>Substitute Disclosure Statement Form (PTO-1449)